DEC 0 6 2001

K012631

# 510(k) Summary of Safety and Effectiveness

**Submitter:** Alliance Medical Corporation
10232 South 51st Street
Phoenix, Arizona 85044

**Contact:** Don Selvey
Vice President, Regulatory Affairs and Quality Assurance
(480) 763-5300

**Date of preparation:** 9 August 2001

**Name of device:** Reprocessed Soft Tissue Ablators

**Common Name:** Soft Tissue Ablators

**Classification Name:** Electrosurgical Cutting and Coagulation Device and Accessories

**Reprocessed device(s):**

| Manufacturer | Description | Model Number |
|---|---|---|
| AthroCare® | Arthro Wand® Right Angle | A 1325-01 |
| AthroCare® | Arthro Wand® Right Angle | A 1330-01 |
| AthroCare® | Arthro Wand® Right Angle | A 1335-01 |
| AthroCare® | Arthro Wand® Right Angle | A 1336-01 |
| AthroCare® | Arthro Wand® Right Angle | A 1345-01 |
| AthroCare® | Arthro Wand® Dome | A 3625-01 |
| AthroCare® | Arthro Wand® Dome | A 3525-01 |
| AthroCare® | Arthro Wand® Dome | A 3630-01 |
| AthroCare® | Arthro Wand® Dome | A 3430-01 |
| AthroCare® | Arthro Wand® Dome | A 3530-01 |
| AthroCare® | Arthro Wand® Bevel | A 2630-01 |
| AthroCare® | Arthro Wand® Bevel | A 2430-01 |
| AthroCare® | Arthro Wand® Bevel | A 2530-01 |
| AthroCare® | Arthro Wand® Small Joint | A 2723-01 |
| AthroCare® | Arthro Wand® Small Joint | A 2823-01 |
| AthroCare® | Arthro Wand® Small Joint | A 1115-01 |
| AthroCare® | Arthro Wand® Bisector | A 4330-01 |
| AthroCare® | Arthro Wand® Straight | A 1125-01 |
| AthroCare® | Arthro Wand® Straight | A 1130-01 |
| AthroCare® | Arthro Wand® Angle | A 1225-01 |
| AthroCare® | Arthro Wand® Angle | A 1230-01 |

| | | |
|---|---|---|
| Mitek® | VAPR™ Thermal Side Effect Electrode (3.5mm) | 225101 |
| Mitek® | VAPR™ Thermal Reversed Angled Side Effect Electrode (3.5mm) | 225112 |
| Mitek® | VAPR™ Thermal Angled End Effect Electrode (3.5mm) | 225104 |
| Mitek® | VAPR™ Side Effect Electrode (3.5mm) | 225301 |
| Mitek® | VAPR™ Angled Side Effect Electrode (21°, 3.5mm) | 225302 |
| Mitek® | VAPR™ End Effect Electrode (3.5mm) | 225303 |
| Mitek® | VAPR™ Angled End Effect Electrode (21°, 3.5mm) | 225304 |
| Mitek® | VAPR™ 90° Hook Electrode (3.5mm) | 225305 |
| Mitek® | VAPR™ Flexible Side Effect Electrode (3.5mm) | 225312 |

**Predicate device(s):**

| | |
|---|---|
| **K000036** | ArthroCare, ArthroCare® ENTec™ ReFlex™ Wand |
| **K000044** | ArthroCare, ArthroCare® Orthopedic Electrosurgery System |
| **K000074** | ArthroCare, ArthroCare® Electrosurgery System |
| **K000228** | ArthroCare® ENTec™ Surgery System |
| **K000511** | ArthroCare® Orthopedic Electrosurgery System |
| **K000936** | Mitek, VAPR™ 2.3mm Wedge Electrode |
| **K001302** | ArthroCare, ArthroCare® Electrosurgery System |
| **K001936** | ArthroCare ENTec® Surgery system, ArthroCare® Orthopedic Surgery System, and ArthroCare® Electrosurgery System (Electrosurgery Systems) |
| **K943450** | ArthroCare, ArthroCare® Arthroscopic Electrosurgery System 970 |
| **K955531** | ArthroCare® Bipolar Loop Electrosurgery System |
| **K960169** | ArthroCare® Urologic Multi-electrode Electrosurgery System |
| **K962445** | ArthroCare® Dental Wand Electrosugery System |
| **K963123** | Arthrocare, ArthroCare® Arthroscopic Electrosurgery System 980 (Model 2000) |
| **K963783** | Mitek, VAPR™ Electrosurgical System |
| **K964849** | ArthroCare® Dermatology Electrosurgery System |
| **K971532** | ArthroCare® Electrosurgery System |
| **K973478** | ArthroCare®, AccENT Head and Neck Electrosurgery System |
| **K974022** | Mitek, VAPR™ T Thermal Electrode |
| **K981870** | ArthroCare® Visage Cosmetic Surgery System |
| **K992180** | ArthroCare® Visage™ Cosmetic Surgery System |
| **K992406** | Mitek, VAPR™ 2.3mm End Effect Electrode |
| **K992581** | ArthroCare, ArthroCare® Orthopedic Electrosurgery System |
| **K992972** | ArthroCare, ArthroCare® Electrosurgery System |

**Device description:** Soft tissue ablators are radiofrequency (RF) surgical tools designed for removal and dissection of tissue in arthroscopic surgeries. A generator or controller serves as the power unit. Soft tissue ablators are available in a wide range of sizes and angles; some models include thermal or suction functions.

**Intended use:**

Reprocessed Soft Tissue Ablators are intended to remove soft tissue and control bleeding by providing tissue ablation and coagulaiton utilizing high-frequency electrical current in patients requiring general or arthroscopic surgery.

**Indications statement:**

Reprocessed soft tissue ablators are to be used in patients requiring arthroscopic surgery of the knee, shoulder, ankle, hip, wrist and elbow to resect, ablate and excise soft tissue.

**Technological characteristics:**

The design, materials, and intended use of the Reprocessed Soft Tissue Ablators are identical to the predicate devices. The mechanism of action of the Reprocessed Soft Tissue Ablator is identical to the predicate devices in that the same standard mechanical design, materials, shapes and sizes are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation.

**Performance data:**

Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of the Reprocessed Soft Tissue Ablators.

- Biocompatibility
- Validation of reprocessing
- Function test(s)

Performance testing demonstrates that Reprocessed Soft Tissue Ablators perform as originally intended.

**Conclusion:**

In accordance with the Federal Food, Drug and Cosmetic Act 21 CFR Part 807 and based on the information provided in this premarket notification, Alliance Medical Corporation concludes that the modified device (the Reprocessed Soft Tissue Ablator) is safe, effective and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 6 2001

Alliance Medical Corporation
Mr. Don Selvey
Vice President
Regulatory Affairs and Quality Assurance
10232 South 51st Street
Phoenix, Arizona 85044

Re: K012631
Trade Name: Reprocessed Soft Tissue Ablators
Regulation Number: 888.1100, 878.4400
Regulation Name: Arthroscope, Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: HRX, GEI
Dated: November 13, 2001
Received: November 20, 2001

Dear Mr. Selvey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walter, MD

Celia M. Witten, Ph.D., M.D.
for Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use Statement

510(k) Number (if ~~known~~): K012631

Device Name: Alliance Medical Corporation Reprocessed Soft Tissue Ablators

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Walker

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K012631

Prescription Use ✓ or Over-the-Counter Use ____
(per 21 CFR 801.109)